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## PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q93343

Hiroyuki NAKAHIRA, et al.

Appln. No.: 10/595,125

Group Art Unit: Unknown

Confirmation No.: 3047

Examiner: Unknown

Filed: August 25, 2004

For:

**BICYCLIC PYRAZOLE DERIVATIVE** 

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

## MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents except US Patents and Patent Publications is submitted herewith.

- U.S. Patent Publication No. 2002-198205 A1, published December 26, 2002 to Himmelsbache et al.
- 2. U.S. Patent Publication No. 2004-077645 A1, published April 22, 2004 to Himmelsbach et al.
- 3. U.S. Patent Publication No. 2004-0087587 A1, published May 6, 2004 to Himmelsbach et al.

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References 1-3 above correspond to WO 02/068420 A1, which was cited in the International Search Report and was previously listed on a PTO/SB/08 A & B.

- 4. U.S. Patent Publication No. 2002-0169174 A1, published November 14, 2002 to Chackalamannil et al.
- U.S. Patent Publication No. 2004-0167137 A1, published August 26, 2004 to
   Chackalamannil et al.
- 6. U.S. Patent Publication No. 2004-0229885 A1, published November 18, 2004 to Chackalamannil et al.
- 7. U.S. Patent Publication No. 2005-0075349 A1, published April 7, 2005 to Chackalamannil et al.
- 8. U.S. Patent No. 6,821,978, issued November 13, 2004 to Chackalamannil et al.

  References 4-8 above correspond to WO 02/24698 A1, which was cited in the International Search Report and was previously listed on a PTO/SB/08 A & B.
- U.S. Patent Publication No. 2004-082570 A1, published April 29, 2004 to Yoshikawa et al.
   Reference 9 above corresponds to JP 2004-43429 A, which was cited in the International Search Report and was previously listed on a PTO/SB/08 A & B.
- 10. WO 02/02560 A2, published January 10, 2002 to Novo Nordisk A/S.
- 11. U.S. Patent Publication No. 2002-0161001 A1, published October 31, 2002 to Kanstrup et al. This reference corresponds to WO 02/02560, listed above.
- 12. U.S. Patent Publication No. 2004-0034014 A1, published February 19, 2004 to Kanstrup et al. This reference corresponds to WO 02/02560, listed above.
- 13. WO 03/004496 A1, published January 16, 2003 to Novo Nordisk A/S.
- 14. U.S. Patent Publication No. 2003/0105077 A1, published June 5, 2003 to Kanstrup et al. This reference corresponds to WO 03/004496, listed above.
- 15. U.S. Patent Publication No. 2005/0148606 A1, published July 7, 2005 to Kanstrup et al. This reference corresponds to WO 03/004496, listed above.

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- 16. WO 03/024965 A2, published March 27, 2003 to Novo Nordisk A/S.
- 17. U.S. Patent Publication No. 2003/0199528 A1, published October 23, 2003 to Kanstrup et al. This reference corresponds to WO 03/024965, listed above.
- 18. L.B. Kundsen et al., "Glucagon-like peptide-1-(9-36) amide is a major metabolite of glucagon-like peptide-1 (7-36) amide after in vivo administration to dogs, and it acts as an antagonist on the pancreatic receptor", European Journal of Pharmacology, Vol. 318, (1996), pp. 429-435.
- 19. T.J. Kieffer et al., "Degradation of Glucose-Dependent Insulinotropic Polypeptide and Truncated Glucagon-Like Peptide 1 in Vitro and in Vivo by Dipeptidyl Peptidase IV", Endocrinology, Vol. 136, No. 8, (1995), pp. 3585-3596.
- R.A. Pederson et al., "Improved Glucose Tolerance in Zucker Fatty Rats by Oral Administration of the Dipeptidyl Peptidase IV Inhibitor Isoleucine Thiazolidide", Diabetes, Vol. 47, (1998), pp. 1253-1258.
- Cellular Peptidases In Immune Functions and Diseases 2, edited by Languer and Ansorge,
   Kluwer Academic/Plenum Publishers, (2000), pp. 111-122, 336-338 and 522.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

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waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: April 28, 2006

233/3 CUSTOMER NUMBER

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Substitute for Form 1449 A & B/PTO				Complete if Known		
E				Application Number	10/595,125	
INFOR	RMATION	DISCLOS	LIRE APS	Confirmation Number	3047	
STATI	EMENT R	Y APPLIC	NT ann	Filing Date	February 27, 2006	
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			1	Examiner Name	Unknown	
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U.S. PATENT DOCUMENTS							
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	No.1	Number	Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		
		US 2002/0198205	Al	12/26/2002	Himmelsbach et al.		
		US 2004/0077645	A1	04/22/2004	Himmelsbach et al.		
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Examiner Cite Initials* No.1	Foreign Patent Document			Publication Date	Name of Patentee or		
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation <sup>6</sup>
		WO	02/02560	A2	01/10/2002	Novo Nordisk A/S	
		WO	03/004496	Al	01/16/2003	Novo Nordisk A/S	
		WO	03/024965	A2	03/27/2003	Novo Nordisk A/S	

		NON PATENT LITERATURE DOCUMENTS			
Examiner Cite Initials* No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.			
		L.B. Kundsen et al., "Glucagon-like peptide-1-(9-36) amide is a major metabolite of glucagon-like peptide-1 (7-36) amide after in vivo administration to dogs, and it acts as an antagonist on the pancreatic receptor", European Journal of Pharmacology, Vol. 318, (1996), pp. 429-435.			
		T.J. Kieffer et al., "Degradation of Glucose-Dependent Insulinotropic Polypeptide and Truncated Glucagon-Like Peptide 1 in Vitro and in Vivo by Dipeptidyl Peptidase IV", Endocrinology, Vol. 136, No. 8, (1995), pp. 3585-3596.			
		R.A. Pederson et al., "Improved Glucose Tolerance in Zucker Fatty Rats by Oral Administration of the Dipeptidyl Peptidase IV Inhibitor Isoleucine Thiazolidide", Diabetes, Vol. 47, (1998), pp. 1253-1258.			
	•	Cellular Peptidases In Immune Functions and Diseases 2, edited by Languer and Ansorge, Kluwer  Academic/Plenum Publishers, (2000), pp. 111-122, 336-338 and 522.			

Examiner Signature	Date Considered	

<sup>•</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.